REMARKS

Claims 1-2 and 4-15 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Makovec et al. (US 5,130,474), in view of Midler et al. (US 5,314,506), and further in view of Green (US 7,122,083).

Applicants respectfully traverse the rejection for the reasons of record and for the following additional reasons.

Specifically, the Examiner refers to page 10 of the specification and asserts that the particle size is relative and not absolute. Thus, it is impossible to compare Applicants' data with the prior art.

Applicants respectfully submit that the Examiner's understanding is incorrect. Page 10 of the specification states "The particle sizes given both in the text and in the claims are not absolute quantities but are relative to the measurement method used (in this case the Malvern Master Sizer 2000 instrument with the method described in Example 1)." This language does not nor was it intended to state that the particle sizes are "relative" and not absolute but was only intended to point out that the particle size measurements depend on the measurement method that is used. Thus, the paragraph is intended to disclose that the particle sizes recited in the specification and claims are based on the method using the Malvern Master Sizer 2000 instrument according to the method of Example 1, as evidenced by the language "(in this case the Malvern Master Sizer 2000 instrument with the method described in Example 1)."

That is, in the present case, the measurement of the particle size distribution (PS) was carried out with the Malvern apparatus according to the wet method using a solvent (tween 20), in which the compound to be analyzed is insoluble.

Since the analysis was carried out under the same conditions for the present invention (Fig. 1A) and the prior art (Fig. 1B), it is submitted that Applicants' data can be compared with the prior art.

Further, it is submitted that the unexpectedly superior results of the present invention has been demonstrated (*see* prior responses, including the Response under 37 C.F.R. § 1.111 filed on March 10, 2009) and that the unexpectedly superior results of the present invention can be understood.

Moreover, a Declaration under 37 C.F.R. § 1.132, in which the differences and unexpected superior results of the crystalline dexloxiglumide obtained by the present invention is demonstrated, is submitted herewith. A product obtained by crystallization from H_2O-EtOH (ratio 2:1) and a product of the present invention obtained by crystallization from isopropyl ether according to Example 1 were analyzed using X-ray diffraction. The sample crystallized from H_2O-EtOH (2:1) contained a much higher percentage of amorphous material (68%), which makes the obtained powder hygroscopic, sticky, and light with poor flowability. As a result, the sample crystallized from H_2O-EtOH (2:1) is not suitable for preparing pharmaceutical oral formulations, specifically tablets.

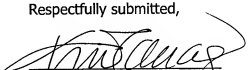
In view of the above, it is respectfully submitted that claims 1-2 and 4-115 are patentable over the cited art.

Accordingly, reconsideration and withdrawal of the rejection is respectfully requested.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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